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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: RICHARD EUSTIS FULTON III and WILLIAM R. DUBRUL	Attorney Docket No.: ARTM 1000-5
Application No.: Unassigned	Examiner: Unassigned
Filed: Concurrently Herewith	Group: Unassigned
Title: BIOPSY LOCALIZATION METHOD AND DEVICE	

BOX PATENT APPLICATION
Assistant Commissioner for Patents
Washington, D.C. 20231

PRELIMINARY AMENDMENT

Dear Sir:

Before the first action in this case, please amend this application as follows. Marked up copies of the amendments to the specification can be found in the attached Appendix.

In The Specification

Page 1, cancel the paragraph at lines 4-9 and substitute the following.

This application is a continuation of application No. 09/366,360 filed June 18, 1999, which application claims the benefit of the following Provisional patent applications. Biopsy Localization Device, Application No. 60/090,243, filed June 22, 1998; Biopsy Localization and Hemostasis Device, Application No. 60/092,734, filed July 14, 1998; Device and Method of Biopsy Localization and Hemostasis, Application No. 60/114,863, filed January 6, 1999; and Device and Method of Biopsy Localization, Hemostasis & Cancer Therapy, Application No. 60/117,421, filed January 27, 1999.

In The Claims

Please cancel Claims 1-52 and add Claims 53-88 as follows.

1 53. A biopsy localization device comprising:
2 a bioabsorbable element in a pre-delivery state prior to its delivery to a
3 soft tissue biopsy site of a patient; and
4 said bioabsorbable element being of a material which is in a post-delivery state
5 at the biopsy site, the bioabsorbable element being at least one of palpably harder than or
6 remotely visualizable within the surrounding soft tissue at the biopsy site when in the post-
7 delivery state.

1 54. The device according to claim 53 wherein the bioabsorbable element has a
2 hardness of at least about 1.5 times as hard as breast tissue in the post-delivery state.

1 55. The device according to claim 53 wherein the bioabsorbable element swells
2 about 50 to 1500 percent from the pre-delivery state to the post delivery state when placed in
3 contact with an aqueous liquid.

1 56. The device according to claim 53 wherein the bioabsorbable element has a
2 longest dimension of at least about 0.5cm when in the post-delivery state.

1 57. The device according to claim 53 wherein the bioabsorbable element
2 comprises a therapeutic agent, the therapeutic agent comprising at least a chosen one of a
3 chemotherapy agent, a radiation agent and a gene therapy agent.

1 58. The device according to claim 53 wherein the bioabsorbable element
2 comprises reservoir means for subsequently receiving a therapeutic agent.

1 59. The device according to claim 58 wherein the reservoir means comprises
2 reservoir means for receiving at least one of a radiation agent, a gene therapy agent and a
3 chemotherapy agent.

1 60. The device according to claim 53 wherein the bioabsorbable element
2 comprises a bioabsorbable filament.

1 61. The device according to claim 53 further comprising a marker element in
2 contact with the bioabsorbable element.

1 62. The device according to claim 61 wherein the marker element is a radiopaque
2 marker element located generally centrally within the bioabsorbable element.

1 63. The device according to claim the 62 wherein the radiopaque marker element
2 is a chosen one of a permanent marker element and a temporary marker element.

64. The device according to claim 53 wherein the bioabsorbable element has margins, said margins being roughened so to help prevent migration of the bioabsorbable element within soft tissue of a patient.

65. The device according to claim 64 wherein the bioabsorbable element has filaments extending from the margins.

66. The device according to claim 65 wherein the filaments are of same material as the bioabsorbable element.

67. The device according to claim 53 wherein the bioabsorbable element is remotely visualizable in its post-delivery state by at least one of ultrasound, mammography and MRI.

68. The device according to claim 53 wherein the bioabsorbable element is softer in its post-delivery state than in its pre-delivery state.

69. A medical device comprising a locatable bioabsorbable element configured for positioning at a biopsy site at the time of taking a tissue sample from the biopsy site.

70. A biopsy localization method comprising:

- taking a tissue sample from a biopsy site within a patient;
- positioning a bioabsorbable element at the biopsy site;
- testing the tissue sample; and
- if the testing indicates a need to do so relocating the biopsy site by finding the bioabsorbable element by at least one of the following:

palpation of the patient to feel the bioabsorbable element;
locating inflammation at the biopsy site caused by the bioabsorbable element;

following a bioabsorbable thread, the thread extending from the patient's skin to the bioabsorbable element; and

remotely visualizing the bioabsorbable element.

71. The method according to claim 70 wherein the positioning step is carried out using said bioabsorbable element and a radiopaque marker.

72. The device according to claim the 71 wherein the radiopaque marker element is a chosen one of a permanent marker element and a temporary marker element.

73. The method according to claim 70 wherein the remotely visualizing step is carried out to by at least one of ultrasound, mammography and MRI.

74. The method according to claim 70 further comprising the step of selecting the bioabsorbable element so that after positioning at the target site, the bioabsorbable element has a hardness of at least about 1.5 times as hard as the surrounding tissue.

75. The method according to claim 74 further comprising the step of effectively preventing blood from contacting the bioabsorbable element until the bioabsorbable element is positioned at the target site, the effectively preventing step being carried out by using a hemostatic bioabsorbable element having a non-hemostatic biodegradable outer layer.

76. The method according to claim 71 further comprising the step of placing a marker element at a generally central location within the bioabsorbable element.

77. A medical treatment method comprising:
 taking a tissue sample from a biopsy site within a patient;
 positioning a bioabsorbable element at the biopsy site at the time of the taking of the tissue sample;
 testing the tissue sample;
 if the testing indicates a need to do so, medically treating the biopsy site.

78. The method according to claim 77 wherein the medically treating step is carried out by at least one of:
 injecting a radiation-emitting element at the vicinity of the target site;
 externally irradiating the target site;
 providing a triggering substance to the agent; and
 removing additional tissue at the target site.

79. The method according to claim 77 wherein the medically treating step comprises delivering a therapeutic agent to the target site.

80. The method according to claim 79 wherein the delivering step is carried out using at least one of:

- a chemotherapy agent;
- a radiation-emitting element;
- thermal energy;
- ionization energy;
- gene therapy;
- vector therapy;
- electrical therapy;
- vibrational therapy; and
- anti-angiogenesis.

1 81. The method according to claim 77 further comprising relocating the biopsy
2 site by finding the bioabsorbable element.

1 82. The method according to claim 81 wherein the relocating step is carried out by
2 a chosen one of palpation and remote visualization.

1 83. The method according to claim 81 wherein the relocating step is carried out by
2 remote visualization using at least one of ultrasound, mammography and MRI.

1 84. The method according to claim 81 wherein the relocating step is carried out
2 prior to the medically treating step.

1 85. The method according to claim 84 wherein the medical treating step comprises
2 removal of tissue.

1 86. The method according to claim 77 wherein the positioning step is carried out
2 using a remotely visulizable bioabsorbable element, and wherein the relocating step comprises
3 guiding a treatment device to the bioabsorbable element by at least one of remote visualization
4 and palpation.

1 87. The method according to claim 77 wherein the medically treating step
2 comprises activating the site locatable by the bioabsorbable element.

1 88. The method according to claim 87 wherein the activating step is carried out by
2 at least one of:

3 injecting a radiation-emitting element at the vicinity of the target site;

4 externally irradiating the target site; and

5 triggering a substance carried by the element.

REMARKS

Claims 53-88 remain in this case.

If the Examiner believes a telephone conversation would aid the prosecution of this case in any way, please call the undersigned at (650) 712-0340.

Respectfully submitted,

Dated: 6 July, 2001.


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APPENDIX

The following is a marked up copy of the amended paragraph at lines 4-9 from page 1 of the specification.

This application is a continuation of application No. 09/366,360 filed June 18, 1999, which application claims the benefit of the following Provisional patent applications. Biopsy Localization Device, Application No. 60/090,243, filed June 22, 1998; Biopsy Localization and Hemostasis Device, Application No. 60/092,734, filed July 14, 1998; Device and Method of Biopsy Localization and Hemostasis, Application No. 60/114,863, filed January 6, 1999; and Device and Method of Biopsy Localization, Hemostasis & Cancer Therapy, Application No. 60/117,421, filed January [25] 27, 1999.